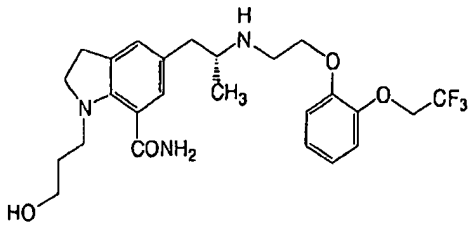
REMARKS

Amended claim 1 is directed to:

a capsule, which comprises:

(1) a granule containing a) as an active ingredient, an indoline compound represented by the formula:



b) D-mannitol and c) partially pregelatinized starch; and

(2) d) a lubricant selected from magnesium stearate, calcium stearate or talc, and e) sodium lauryl sulfate,

wherein 85% dissolution time is not more than 15 minutes in a dissolution test according to method 2 (paddle method) of Japanese pharmacopoeia in a condition using water as a test medium and a paddle speed of 50rpm.

The capsule of the present invention exhibits immediate dissolution capability in water in which the active ingredient (KMD-3213) is barely soluble, and has excellent therapeutic activity in the treatment of dysuria. The capsule of the present invention also has excellent storage stability and high filling precision where variations in the contained amount of the active ingredient are very small. The capsule of the present invention is suitable for industrial production.

New Matter Rejection

The Examiner finds "a granular material" and "partially pregelatinized starch" to represent new matter.

For "a granular material", see: page 12, line 27; page 13, line 1; page 14, line 5; page 15, lines 8, 10, 15 and 16, etc.

For "partially pregelatinized starch", see page 12, lines 8-13; page 28, lines 9-10; Tables 3, 4 and 5 and page 34, line 9.

However, Applicants do further respond by amending the phrase "a granular material" in claim 1 into "a granule". Such finds its support on page 34, lines 8 to 16 and page 35, lines 7 to 15 in Examples 1 and 2 of the present specification:

Support also occurs at page 19, lines 9-16 in the specification:

"capsules can be prepared as follows. KMD-3213 ...is admixed with a filler, preferably D-mannitol ...and disintegrator. Then, the mixture is kneaded ...and sieved to prepare a granule".

"..KMD-3213, ...D-mannitol, ...and ...partially pregelatinized starch ...were mixed sufficiently. ...and the mixture was granulated. The granule was dried ...and sieved."

Withdrawal is requested.

Indefiniteness Rejection

Regarding the indefiniteness rejection based on "partially", Applicants respond by submitting brochures on the two commercially available partially pregelatinized starches of PCS and Starch 1500 and a copy of "Japanese Pharmaceutical Excipients 1993", 1994, p. 263-264 to prove that the term "partially pregelatinized starch" is conventional and well known to those of

ordinary skilled in the art. PC-10 in the Asahi Kasei brochure is the trade name in the U.S. corresponding to PCS in Japan.

In the PCS brochure, it is clearly described that partially pregelatinized starches are manufactured by the thermal treatment of raw corn starch, and that partial pregelatinization provides Starch 1500 and PCS with their unique properties. It is also described that both Starch 1500 and PCS meet the requirements of JPE (the abbreviation for the publication "Japanese Pharmaceutical Excipients"), for partially pregelatinized starch.

JPE is a world-famous publication well known to those of ordinary skill in formulation technology, which contains a number of monographs including the names of ingredients or preparations; definitions; packaging, storage, and labeling requirements; and specifications. The specifications consist of a series of tests, procedures for the tests, and acceptance criteria. Applicants submit a monograph on partially pregelatinized starch as described in JPE that was published in 1994 prior to the present application's filing date.

Applicants submit that partially pregelatinized starch is a conventional term prior to the present application's filing date, and one of ordinary skill in the art would understand what is claimed by the term "partially pregelatinized starch" and would be reasonably apprised of the scope of the invention in view of the prior art.

Withdrawal is requested.

The Prior Art

Kitazawa et al (Kitazawa-previous); Ishihara et al (Ishihara-previous); U.S. 4,757,090 Salpekar et al (Salpekar); U.S. 5,370,878 Shah (Shah).

The Rejection

Claims 1, 8, 9, 11, 12 and 27 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kitazawa in view of Ishihara and in further view of Salpekar and Shah.

The Examiner's position is set forth in the Action and will not be repeated here except as necessary to an understanding of Applicants' traversal which is now presented.

Traversal

The Teaching of Kitazawa

Kitazawa discloses KMD-3213 is useful as a therapeutic agent for treating dysuria (cols. 49-50 as Compound 40). Kitazawa fails to teach or suggest the capsule of the present invention or the advantageous effects of the present capsule.

The Teaching of Ishihara

The invention of Ishihara is directed to agents for improving the potency of the urinary bladder. Ishihara discloses several formulation examples on page 51, and pages 55-56 as Formulation Examples 1-6 in the specification. The dosage forms and compositions of Formulation Examples 1-6 are all quite different from those of the capsule of the present invention.

Ishihara also makes general mention regarding Formulations, Administration Routes and Dosages on pages 43-46. Ishihara teaches a variety of organic or inorganic carrier materials conventionally employed as pharmaceutical materials such as bulking agents, lubricants, binders, and disintegrators for solid preparations. A number of ingredients for bulking agents, lubricants, binders, and disintegrators are listed in the specification.

Ishihara fails to teach or suggest the capsule of the present invention or the advantageous effects of the present capsule.

The Disclosure of Salpekar

The invention of Salpekar is directed to an N-acetyl-p-aminophenol composition containing pregelatinized starch useful in direct tabletting. Salpekar discloses a particulate N-acetyl-p-aminophenol composition comprising as components:

(a) from about 84 to 94 percent, based on the dry weight of the composition, of N-acetyl-p-aminophenol,

(b) from about 5 to about 15 percent, based on the dry weight of the composition, of a pharmaceutically acceptable pregelatinized starch, and

(c) water.

Salpekar fails to teach or suggest the capsule of the present invention or the advantageous effects of the present capsule.

The Disclosure of Shah

The invention of Shah is directed to a method for preparing granulated acetaminophen compositions suitable for direct compression into tablets. Shah discloses a method for preparing a free-flowing particulate granulated acetaminophen composition, which comprises:

(A) blending a mixture of (a) from about 70 to about 95 percent of acetaminophen by dry weight of the blend, (b) from about 1 to about 10 percent of binder by dry weight of the blend, (c) from about 0.5 to about 3 percent of lubricant by dry weight of the blend, (d) from about 0 to about 2 percent of disintegrating agent by dry weight of the blend, and (e) from about 1 to about 7 percent of a liquid selected from the group consisting of water, methanol, ethanol, isopropanol and mixtures thereof by dry weight of the blend;

(B) compacting the blend of Step A to form a compact; and

(C) milling the compact Step B to form the said granulated acetaminophen composition.

Shah fails to teach or suggest the capsule of the present invention or the advantageous effects of the present capsule.

Patentability over Kitazawa in view of Ishihara and further in view of Salpekar and Shah

As the Examiner states on page 4 of the Action: "Kitazawa et al., and Ishihara et al...., differs from the instant claims insofar it does not teach a capsule comprising partially pregelatinized starch wherein 85% dissolution time is not more than 60 minutes."

As Kitazawa and Ishihara fail to teach or suggest the capsule of the present invention and the advantageous effects of the present capsule, the capsule of the present invention is not obvious over Kitazawa and Ishihara.

Regarding Salpekar and Shah, it is described on page 2, line 66 to page 3, line 4 in Shah that:

"It is usually marketed in 325 mg and 500 mg tablets of various shapes and sizes. These tablets have a high dosage level of the drug and are large in size. Accordingly, the tablet blend must contain a high weight percentage of acetaminophen".

Similar disclosure occurs in Salpekar.

Thus, the compositions of Salpekar and Shah both have as an essential feature the presence of a high weight percentage of acetaminophen, e.g. about 70 to 95 percent by dry weight of the compositions. Moreover, both of the compositions of Salpekar and Shah are directed to a granulated acetaminophen composition suitable for direct compression into tablets.

In order to demonstrate that the capsule of the present invention is unobvious over Salpekar and Shah, Applicants have conducted comparative tests as set out in the Declaration under 37 C.F.R §1.132 submitted December 1, 2008.

In the comparative tests, Applicants firstly prepared a granulated composition containing KMD-3213 instead of acetaminophen in accordance with the same composition as exemplified as Example 1 in Salpekar and Shah, and then filled the granulated composition into a capsule shell to prepare comparative capsules 1A and 2A. Applicants also prepared comparative capsules 1B and 2B using a granulated composition containing KMD-3213, partially pregelatinized starch and sodium lauryl sulfate that is taught by Salpekar at col. 3, lines 13-23.

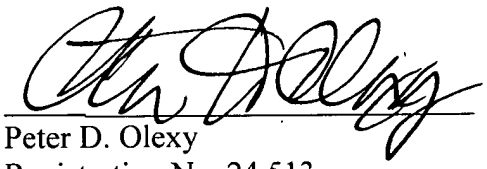
The results of dissolution tests clearly show that the capsules of Examples 1 and 2 of the present application have much higher dissolution rates as compared with those of the comparative capsules 1A and 2A which do not contain sodium lauryl sulfate. Further, the capsules of Examples 1 and 2 of the present application also have much higher dissolution rates as compared with those of the comparative capsules 1B and 2B which contain sodium lauryl sulfate. All of the comparative capsules showed a less than 40% dissolution rate at 30 minutes after starting the test while the capsules of Examples 1 and 2 of the present application showed a more than a 90% dissolution rate at 15 minutes after starting the test. Applicants believe that one of ordinary skill in the art could not predict such advantageous effects achieved by the capsule of the present invention from the teaching of granulated acetaminophen compositions of Salpekar and Shah.

In the previously submitted Declaration under 37 C.F.R §1.132, (March 31, 2008) Applicants demonstrated that the capsule of the present application is not obvious over Kitazawa in view of Ishihara. As described above, the invention of Ishihara is directed to agents for improving the potency of the urinary bladder while the invention of Salpekar and Shah is directed to a granulated composition containing a high weight percentage of acetaminophen suitable for direct compression into tablets. There is thus no motivation to

combine Ishihara with Salpekar and Shah to reach a capsule containing KMD-3213. Further, even in the case of combining the teaching of Ishihara with Salpekar and Shah, one of ordinary skill in the art could not predict the unexpected effects of exhibiting an immediate dissolution property in water and excellent storage stability and high filling precision achieved by the present capsules.

Therefore, Applicants believe that the capsules of the present invention are not obvious over Kitazawa in view of Ishihara and in further view of Salpekar and Shah.

Respectfully submitted,



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WASHINGTON OFFICE
23373
CUSTOMER NUMBER

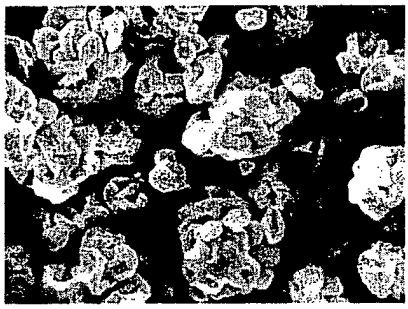
Date: December 5, 2008

PCS®

Pregelatinized starch PCS®

CEOLUS®
CELPHERE®
PCS®
Trehalose
Kiccolate®

PCS® is a natural excipient manufactured by thermal treatment of raw corn starch. It is inert, high in water-absorbing, and has pH-independent disintegrating properties. It swells in water, rather than dissolving.



USP / NF	Ph.Eur.	JPE
Pregelatinized Starch	Pregelatinized Starch	Partly Pregelatinized Starch

>>Typical properties >>Features and functions >>Package

Typical properties of PCS® PC-10

Average particle size	70μm	Water-soluble content	≤3%
Repose angle	38-40 Degree	water-holding capacity	3.7 g/g
Bulk density	0.5g/cm^3	Swelling volume in water	8-9 cm^3/g

Note: All values are presented only for the purpose of basic reference and not as specifications.

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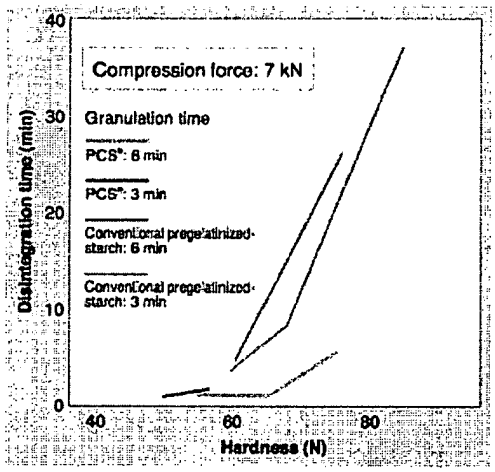
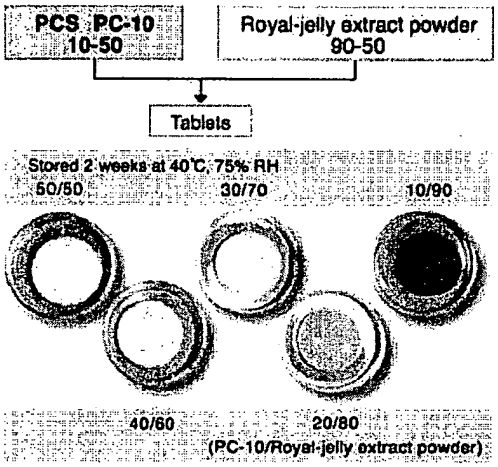
Features and functions

- **Stabilizer for moisture-sensitive drugs**
- **Dissolution enhancer**
- **Carrier for hygroscopic ingredients**
- **Granulation aid**
- **High flowability**

Tablet hardness vs. disintegration time



Royal-jelly extract stabilization



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Package

- **Polyethylene bag in kraft paper bag**
- **20kg net weight**

Go To Top

JAPANESE PHARMACEUTICAL EXCIPIENTS

1993

Edited by

The Japan Pharmaceutical Excipients Council

YAKUJI NIPPO, LTD.

Japanese Pharmaceutical Excipients 1993 (JPE 1993)
IBSN4-8408-0324-2 C-3047

Printed in Japan

RECOMMENDATION

Coupled with highly improved and diversified technology for pharmaceutical preparations in recent years, the role of pharmaceutical excipients to be played in stabilization and expansion of the application of those articles to practical uses has been increasing with years, which has led to a demand for ensuring their quality with the establishment of standards.

Along this line, the standards of pharmaceutical excipients have long been prepared in the Ministry of health and Welfare in continuous efforts for ensuring the quality of pharmaceutical excipients and for engaging efficiently in the review processing of their approval. This new book came out with the title of "the Japanese Pharmaceutical Excipients 1993" (JPE 1993) which listed the specifications for pharmaceutical excipients not included in the Japanese Pharmacopoeia.

The number of articles listed in the JPE 1993 is totaled to 206 pharmaceutical excipients currently in common use, and we are in the process of preparing specifications for additional articles successively.

Now, the English version of the book appeared on this occasion with the cooperation of the members of the Japan Pharmaceutical Excipients Council. There is today a demand for international harmonization for standards for drugs. As such practical circumstances require, we are sincerely pleased that the book on pharmaceutical excipients has been published just at the good time. We believe that this new English edition will be a useful service to concerned parties and people in Japan and abroad.

June, 1994

Kunikazu Teshima
Director
Pharmaceuticals and Cosmetics Division
Pharmaceutical Affairs Bureau
Ministry of Health and Welfare

Operating conditions—

Detector: A thermal conductivity detector.

Column: A stainless steel column 3 mm in inside diamter and 3 m in length, packed with 149 – 177-μm siliceous earth for gas chromatography as carrier, coated with polyethylene glycol 400 at the ratio of 30%.

Column temperature: A constant temperature of about 95°.

Carrier gas and flow rate: Helium; adjust the flow rate so that the retention time for *n*-propanol is between 7 and 9 minutes at the column temperature and in a constant amount of the carrier gas (not more than 1.5%).

Loss on drying Not more than 6.0% (1 g, 105°, 3 hours).

Residue on ignition Not more than 2.0% (1 g).

Storage Preserve in well-closed containers.

Administration route Oral administration, general external preparation, ophthalmic preparation, dental exterual use and troche use.

Note Indicate the viscosity of a product for practical use.

108906

Partly Pregelatinized Starch

PCS

Partly Pregelatinized Starch is obtained by heating Corn Starch (JP) with water under ordinary or increased pressure, partially pregelatinizing starch grains, and drying.

Description Partly Pregelatinized Starch occurs as a white to yellowish white, odorless and tasteless powder.

Under a microscope, it reveals spherical or polygonal simple grains without ridge; often gathers to form compound grains.

On the addition of water, it swells, and becomes a white-turbid liquid.

It is practically insoluble in ethanol.

Identification **(1)** To 1 g of Partly Pregelatinized Starch add 50 ml of water, and stir well: a white-turbid liquid is produced.

(2) To the solution obtained in (1) add 1 to 2 drops of iodine TS: a purple to red-purple color develops.

(3) Boil the solution obtained in (1), and allow to cool: a turbid, pasty liquid is produced.

Purity **(1)** Acid or alkali—The pH of the solution obtained in the Idenification (1) is between 4.0 and 7.0.

(2) Chloride—To 3.5 g of Partly Pregelatinized Starch add 160 ml of water, stir well to make a homogeneous liquid, shake for 10 minutes, add 7 ml of dilute nitric acid and water to make 200 ml, and centrifuge. Boil 100 ml of the supernatant liquid with condenser for 20 minutes, cool, and add water to make 100 ml. To 20 ml of this solution add 10 ml of dilute nitric acid and water to make 50 ml. Perform the test using this solution as the test solution. Prepare the control solution as follows: to 0.30 ml of 0.01 N hydrochloric acid VS add 10 ml of dilute nitric acid and water to make 50 ml (not more than 0.030%).

(3) Heavy metals—To 1.0 g of Partly Pregelatinized Starch add 2 ml of a solution of magnesium sulfate (1 in 4), evaporate on a water bath to dryness, and heat gently to carbonize. After cooling, add 1 ml of sulfuric acid, heat carefully, and heat strongly between 550° and 600° to incinerate. If a carbonized material remains, moisten with a small amount of sulfuric acid, and repeat the above procedure. After cooling, add 2 ml of hydrochloric acid, evaporate on a water bath to dryness, moisten the residue with 3 drops of hydrochloric acid, add 10 ml of hot water, and warm for 2 minutes. To this solution add 1 drop of phenolphthalein TS, then add ammonia TS dropwise until a pale red color develops, add 2 ml of dilute acetic acid, filter if neces-

sary, and wash with 10 ml of water. Transfer the combined filtrate and washing to a Nessler tube, and add water to make 50 ml. Perform the test using this solution as the test solution. Prepare the control solution as follows: to 2 ml of a solution of magnesium sulfate (1 in 4) add 1 ml of sulfuric acid and 2 ml of hydrochloric acid, evaporate on a water bath, then evaporate on a sand bath to dryness, moisten the residue with 3 drops of hydrochloric acid, proceed in the same manner as the preparation of the test solution, and add 2.0 ml of Standard Lead Solution and water to make 50 ml (not more than 20 ppm).

(4) Arsenic—Prepare the test solution with 1.0 g of Partly Pregelatinized Starch according to Method 3, and perform the test using Apparatus B. Take 10 ml of a solution of magnesium nitrate in ethanol (1 in 10), add 10 ml of dilute hydrochloric acid, and dissolve by warming on a water bath. Control solution: proceed with 2.0 ml of Standard Arsenic Solution, instead of Partly Pregelatinized Starch, in the same manner as the test solution (not more than 2 ppm).

(5) Sulfurous acid—To 20 g of Partly Pregelatinized Starch add 200 ml of a solution of sodium sulfate (1 in 5), shake, and filter. To 100 ml of the filtrate add 3 ml of starch TS, and titrate with 0.02 N iodine VS until a persistent blue color develops: the volume is not more than 0.5 ml (not more than 0.003%).

(6) Oxidizing substances—To 5.0 g of Partly Pregelatinized Starch add 20 ml of dilute ethanol, stir with 1 ml of acetic acid to make a homogeneous suspension. To this suspension add 0.5 ml of a freshly prepared saturated solution of potassium iodide, stir, and allow to stand for 5 minutes: no blue, brown or purple color develops.

Loss on drying Not more than 13% (1 g, 105°, 3 hours).

Residue on ignition Not more than 0.5% (2 g).

Storage Preserve in well-closed containers.

Administration route Oral administration, general external preparation.

105169

Phosphoric Acid

H_3PO_4: 98.00

Phosphoric Acid contains not less than 85.0% of H_3PO_4.

Description Phosphoric Acid is a clear, colorless and viscous liquid. It is odorless. On preserving at a low temperature, it may solidify.

It is miscible with water and with ethanol.

Specific gravity d_4^{20}: not less than 1.69.

Identification To a solution of Phosphoric Acid (1 in 20) add 2 to 3 drops of phenolphthalein TS, and neutralize with sodium hydroxide TS: the solution responds to the Qualitative Tests for phosphate.

Purity (1) Sulfate—Dissolve 5 g of Phosphoric Acid in water to make 50 ml, and use this solution as the sample solution. Perform the test with 6 ml of the sample solution. Prepare the control solution with 0.35 ml of 0.01 N sulfuric acid VS (not more than 0.028%).

(2) Nitrate—To 5 ml of the sample solution obtained in (1) add 0.1 ml of indigo carmine TS and 5 ml of sulfuric acid: a blue color, which does not disappear within 1 minute, develops.

(3) Heavy metals—To 30 ml of the sample solution obtained in (1) add 2 drops of phenolphthalein TS, and add ammonia TS dropwise until a faint, red color develops. To this solution add 2 ml of dilute acetic acid and water to make 50 ml, and perform the test. Prepare the control solution with 1.5 ml of Standard Lead Solution (not more than 5 ppm).

(4) Arsenic—Prepare the test solution with 4.0 g of Phosphoric Acid according to Method 1, and perform the test using Apparatus B (not more than 0.5 ppm).

(5) Phosphate—Take 1.0 ml of Phosphoric Acid in a glass-stoppered measuring cylinder, add 6 ml of ether and 2 ml of ethanol, and shake: no turbidity occurs.

(6) Potassium permanganate-reducing substances—Dissolve 7.0 g of Phosphoric Acid in 5 ml of water, add 0.20 ml of 0.1 N potassium permanganate VS, and heat on a water bath: the color of the solution does not disappear within 10 minutes.

Assay To about 1 g of Phosphoric Acid, accurately weighed, add 25 ml of water and 5 g of sodium chloride, cool to 15°, and titrate with 1 N sodium hydroxide VS (indicator: 5 drops of thymolphthalein TS).

Each ml of 1 N sodium hydroxide VS = 49.00 mg of H_3PO_4

Storage Preserve in tight containers.

EXCIPIENTS

STARCH 1500 G

PARTIALLY PREGELATINIZED MAIZE STARCH

Information Sheet

Starch 1500 G is a unique, global pharmaceutical excipient combining several properties in a single product. Starch 1500 G performs the multiple functions of a binder, disintegrant, flow-aid and self-lubricant. It is extremely versatile, being effective in a variety of processing methods for solid oral dosage forms.

	Direct Compaction	Wet Granulation	Capsule Plug Formation
Binder	X	X	X
Disintegrant	X	X	X
Flow Aid	X	X	X
Lubricant	X	X	X

Binder

- Functions as both a wet and dry binder to allow process flexibility.
- Enhances the functionality of other excipients to produce tablets with excellent hardness and low friability.
- Reduces process costs associated with the preparation of typical binder solutions.

Disintegrant

- Provides effective disintegration and eliminates the need for costly super disintegrants, which can reduce film coating quality.

Flow-Aid

- Excellent flow properties ensure drug content and weight uniformity of tablets and capsules.

Lubricant

- Self-lubricating property eliminates any negative effect on dissolution or film coating quality seen with other lubricants.

Regulatory

- Meets PhEur and USP/NF specifications for pregelatinized Starch and JPE requirements for partly pregelatinized Starch

Botanical Source

- Maize (does not contain gliadin gluten)

Novel Applications

- Moisture Sensitive Actives:
  Supports long-term stability
- Low Dose Actives:
  Delivers superior drug uniformity
- Film Coated Tablets:
  Enhances coating performance and productivity
- Controlled Release:
  Improves flow properties of HPMC matrix formulations

Technical Support

- Worldwide network of technical service laboratories
- Formulation and application development
- Scale-up support

Packaging

- Starch 1500 is packaged in 50 kg fiber drums fitted with a polyethylene liner.

For more information on Starch 1500® visit our web site at www.colorcon.com/excipients

Colorcon

World Headquarters
Colorcon
415 Moyer Blvd., P.O. Box 24, West Point, PA 19486-0024
Tel: 215-699-7733 Fax: 215-661-2605 Web Site @http://www.colorcon.com

Locations	Telephone	Facsimile
United States		
Santa Ana, California	714-549-0631	714-549-4921
Indianapolis,Indiana	317-545-6211	317-545-6218
Humacao, Puerto Rico	787-852-3815	787-852-0030
Europe		
Dartford, Kent, England	44-1322-293000	44-1322-627200
Bougival, France	33-1-3082-1582	33-1-3082-7879
Idstein, Germany	49-6126-9961-0	49-6126-9961-11
Gallarate, Italy	39-0331-776932	39-0331-776831
Budapest, Hungary	36-1-200-8000	36-1-200-8010
Istanbul, Turkey	90-216-465-0360	90-216-465-0361
Barcelona, Spain	34-9-3589-3756	34-9-3589-3792

Locations	Telephone	Facsimile
Asia/Pacific		
Singapore	65-6438-0318	65-6438-0178
Fuji-gun, Shizuoka, Japan	81-5-4465-2711	81-5-4465-2730
Shanghai, China	86-21-5442-2222	86-21-5442-2229
Goa, India	91-0832-2883434	91-0832-2883440
Seoul, Korea	822-2057-2173	822-2057-2179
Latin America		
Buenos Aires,Argentina	54-11-4552-1565	54-11-4552-3997
Cotia, Brasil	55-11-4612-4262	55-11-4612-3307
Bogota, Colombia	571-418-1202	571-418-1257
Caracas, Venezuela	58-212-793-3459	58-212-781-2619
Santa Fe, Mexico	52-55-5292-1611	52-55-5292-1750

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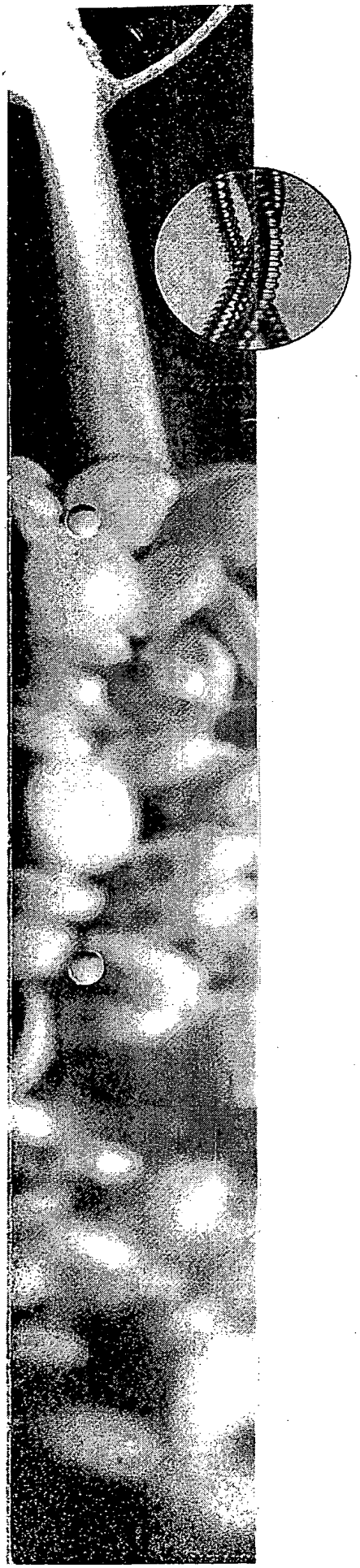


STARCH 1500®

PARTIALLY PREGELATINIZED MAIZE STARCH

Flexibility for performance

Colorcon®

STARCH 1500®
PARTIALLY PREGELATINIZED MAIZE STARCH

THE SUPERIOR MULTIFUNCTIONAL EXCIPIENT FOR SOLID DOSAGE DEVELOPMENT

Starch 1500 is a unique pharmaceutical excipient combining several properties in a single product. Only Starch 1500 performs the multiple functions of a binder, disintegrant, flow-aid and self-lubricant. It is extremely versatile, being effective in a variety of processing methods for solid oral dosage forms. Starch 1500 also exhibits synergy, enhancing the functionality of other commonly used excipients in formulations.

MULTIFUNCTIONAL

Provides a unique range of functions:

- Binder
- Disintegrant
- Flow-Aid
- Lubricant

VERSATILE

Flexible performance in a variety of applications:

	DIRECT COMPACTION	WET GRANULATION	CAPSULE PLUG FORMATION
Binder	X	X	X
Disintegrant	X	X	X
Flow-Aid	X	X*	X
Lubricant	X	X*	X

*In the extra granular phase

COST-EFFECTIVE

Cuts process and material costs by reducing or eliminating:

- Excess binders
- Superdisintegrants
- Additional lubricants and glidants
- Manufacturing steps

MANUFACTURED FOR THE PHARMACEUTICAL INDUSTRY

- Manufactured in modern cGMP facilities dedicated solely to the production of pharmaceutical excipients

INDUSTRY LEADING TECHNICAL EXPERTISE

- Worldwide manufacturing, distribution and technical service facilities
- Formulation and application development support
- Global regulatory assistance
- Innovative new product development

DIRECT COMPACTION

Starch 1500 performs key functions in direct compaction formulations as a binder, disintegrant, flow-aid and self-lubricant. It also promotes formulation flexibility by complementing and enhancing the functionality of other excipients.

BINDER

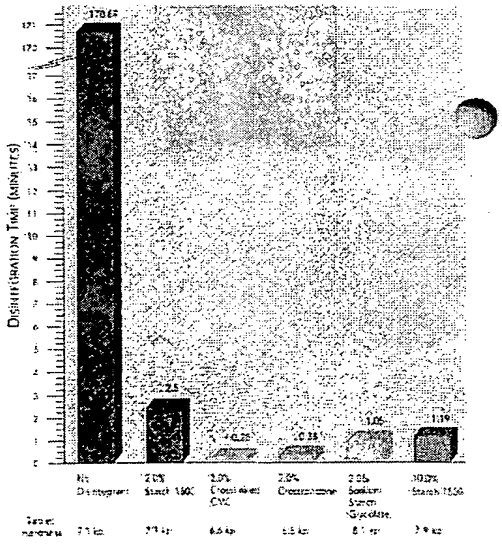
As a dry binder, it compresses well, predominately deforming plastically. Starch 1500 can be used with other excipients, such as microcrystalline cellulose, lactose, and dicalcium phosphate, to produce tablets with excellent hardness and low friability at compaction forces typically used in tableting operations.

DISINTEGRANT

Starch 1500 performs the actions of two disintegrants; maize starch and free amylose in dry processes. In some applications, 2% to 10% of Starch 1500 provides disintegrant action as effective as super disintegrants, greatly reducing costs. (See Figure 1)

Figure 1

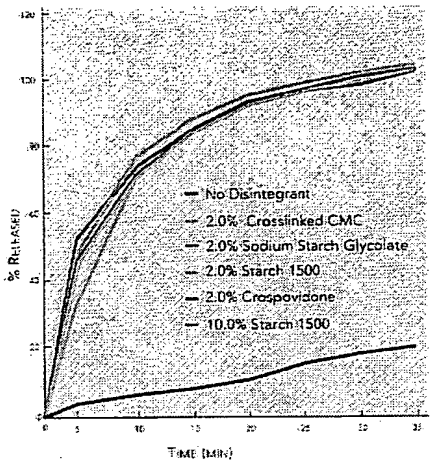
DISINTEGRATION PROFILE FOR HYDROCHLOROTHIAZIDE TABLETS, 50 MG **



The combination of maize starch and free amylose has a positive impact on drug dissolution. Supporting the tablet disintegration data in Figure 1, the resulting drug dissolution data in Figure 2 compares Starch 1500 with more costly disintegrants.

Figure 2

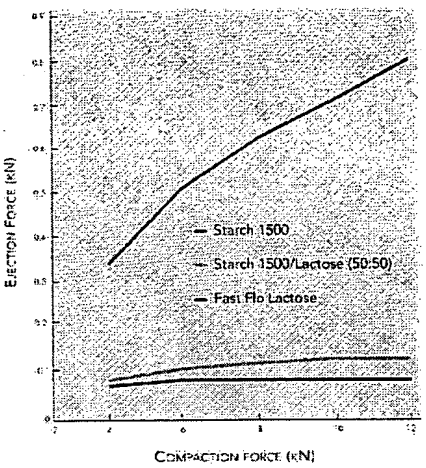
DISSOLUTION PROFILE FOR HYDROCHLOROTHIAZIDE TABLETS; 50 MG**



** Tablets were formulated with 25% hydrochlorothiazide, 0.25% magnesium stearate, and equal parts lactose and dicalcium phosphate. Equal portions of the lactose and dicalcium phosphate were substituted with 2% or 10% Starch 1500.

Figure 3

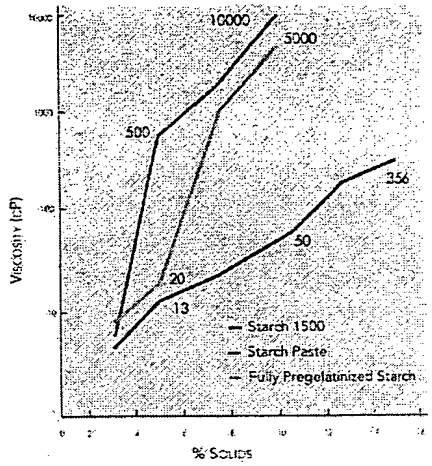
EJECTION FORCE VALUES FOR HYDROCHLOROTHIAZIDE TABLETS



Hydrochlorothiazide 25%, excipient 74.75%, 0.25% magnesium stearate as lubricant

Figure 4

CONCENTRATION DEPENDENT VISCOSITY PROFILES



Traditional starch paste at 85°C compared to Starch 1500 and a fully pregelatinized starch prepared in cold water

FLOW-AID

Starch 1500 provides excellent flow properties, demanded by today's high-speed tableting and capsule filling equipment; ensuring that manufacturers can produce tablets and capsules with consistent uniform weight and drug content.

SELF LUBRICANT

The high inherent lubricity of Starch 1500 enables the formulator to lower the levels of traditional lubricants, such as magnesium stearate. For example, magnesium stearate added in high levels, or when over-blended, can slow dissolution and cause problems with compaction (soft tablets) and film coating (poor film adhesion). Therefore, Starch 1500 enables lubricant levels and their potential problems to be reduced or eliminated. (See Figure 3)

WET GRANULATION

In wet granulation applications, Starch 1500 exhibits dual functionality as both binder and disintegrant as a result of partial cold water solubility. Starch 1500 allows process flexibility: it can be dry-blended with other ingredients before adding water, or a portion can be dispersed in cold water. A slurry of Starch 1500 in cold water provides effective binding properties at higher solids and lower viscosity than traditional starch pastes, which must be heated and prepared at lower concentrations. (See Figure 4) Processing costs are reduced by eliminating the time and expense of preparing traditional binder solutions. In addition, granulations using Starch 1500 as a binder give excellent tablet hardness and fast disintegration.

In fluid bed granulations, Starch 1500 alone can be used as both binder and disintegrant. For example, capsule-shaped acetaminophen tablets, 500mg, of excellent hardness and friability values of less than 0.19% were produced through the simple formulation of 85% acetaminophen and 15% Starch 1500 used as the wet granulation binder. In this formulation, Starch 1500 functioned as an exceptional disintegrant with disintegration time less than 1 minute. Dissolution was excellent. Test results showed 80% drug release within 5 minutes. In addition, the low viscosity of Starch 1500 in cold water allowed higher binder content solutions and faster spray times, resulting in reduced process times.

Capsule Plug Formation

Starch 1500, as a flow-aid, improves uniformity of capsule fill. As a binder, Starch 1500 facilitates plug formation in dosator-type equipment and reduces powder fallout when the plug is transferred. The inherent lubricity of Starch 1500 means a lower force to eject material into the capsule shell (compared to other excipients) and leads to reduced wear on dosator-type equipment.

Starch 1500 Product Range

Colorcon has made Starch 1500 even more versatile by developing a line of products for optimal performance applicable to a variety of formulations. The Starch 1500 product range is produced exclusively for the pharmaceutical industry under cGMP guidelines. Starch 1500 products are designed to meet regulatory needs worldwide. Specific products conform to the USP/NF, Ph.Eur. and JPE compendial monographs.

COLORCON

SUPPLIER OF CHOICE

Colorcon has a firm commitment to providing products and services for high quality coating systems and formulated products along with technical support dedicated to meeting customers' needs. In addition, a focus on market issues and technology development has earned Colorcon an international reputation in the pharmaceutical industry as the supplier of choice.

Colorcon's worldwide network of technical service laboratories and experts bring solutions to our customers when and where they are needed. These resources serve all aspects of customer projects including; formulation development, application development, scale-up support and regulatory information. We understand the impact of speed to market in the competitive fast paced pharmaceutical industry and support our customers in the production of highly effective formulations in reduced time frames.

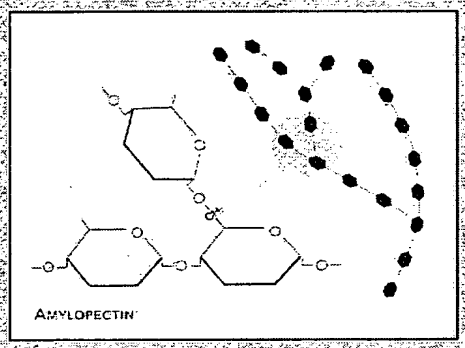
Take advantage of our experience, technology and creativity; enhance your position in the marketplace.

Make Colorcon your partner, your supplier of choice.

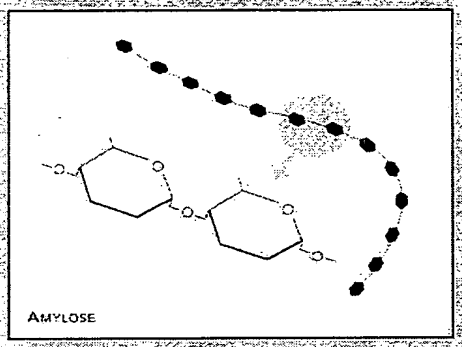
Unique Manufacturing Process

Starch 1500 is a partially pregelatinized maize starch manufactured exclusively for the pharmaceutical industry in dedicated cGMP facilities. The process involves a physical modification of the starch (no chemical additives or surfactants are used), resulting in the combined benefits of the soluble and insoluble functionality of Starch 1500.

Maize starch is composed of two polymers, amylose and amylopectin which are tightly bound in a specific spherocrystalline structure. Through partial pregelatinization, the bond between a portion of the two polymers is broken, providing Starch 1500 with its unique properties. The process results in partial solubility, increased particle size, improved flow properties and compactability.



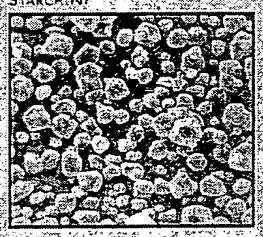
Amylopectin has a branched-chain molecular structure, which makes it readily soluble in cold water. Amylopectin functions as a binder in wet granulation processes.



Amylose has a straight-chain molecular structure, which exhibits a very strong intermolecular bonding capability. Amylose swells significantly when wetted, giving it excellent disintegrating characteristics.

One Excipient, Multiple Functions

STARCH NF



STARCH 1500®

Colorcon's unique manufacturing process results in the most effective functional balance for Starch 1500, providing good cold water binding and granulation properties, yet retaining effective tablet disintegrant properties. The physical structure of Starch 1500 also imparts good compactability, flow and lubrication capabilities.

These multifunctional properties can be utilized in a variety of applications, including direct compaction, wet granulation, fluid bed granulation and capsule plug formation. The distinct benefits of Starch 1500 can bring significant process flexibility to solid dosage forms.

SEM photo of Starch 1500 shows individual starch grains along with aggregates bonded to the hydrolyzed starch. Starch 1500 has better flow characteristics than Starch NF and has much higher compactability. Photos shown at 10 microns.

STARCH 1500®

PARTIALLY PREGELATINIZED MAIZE STARCH

- Multifunctional for formulation versatility
- Flexibility for performance in a variety of applications
- Manufactured exclusively for the pharmaceutical industry
- Meets global regulatory requirements

WORLD HEADQUARTERS

COLORCON
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Tel: 215-699-7733 Fax: 215-661-2605

LOCATIONS	TELEPHONE	FACSIMILE
UNITED STATES		
Santa Ana, California	714-549-0631	714-549-4921
Indianapolis, Indiana	317-545-6211	317-545-6218
Humacao, Puerto Rico	787-852-3615	787-852-0030
EUROPE		
Dartford, Kent, England	44-1322-293000	44-1322-627200
Bougival, France	33-1-3082-1582	33-1-3082-7879
Idstein, Germany	49-6126-9961-0	49-6126-9961-11
Gallarate, Italy	39-0331-776932	39-0331-776831
Budapest, Hungary	36-1-200-8000	36-1-200-8010
Barcelona, Spain	34-9-3589-3756	34-9-3589-3792
ASIA/PACIFIC		
Singapore	65-438-0318	65-438-0178
Shanghai, China	86-21-6489-2222	86-21-6489-2223
Mumbai, India	91-22-868-2537	91-22-868-4518
Tokyo, Japan	81-3-5248-0581	81-3-5248-0547
LATIN AMERICA		
Buenos Aires, Argentina	54-11-4552-1565	54-11-4552-5158
Bogota, Colombia	571-418-1202	571-418-1190
Santa Fe, Mexico	525-292-1611	525-292-1750
Caracas, Venezuela	58-2-442-4819	58-2-442-6340

VISIT COLORCON ONLINE AT www.colorcon.com

EX/STAR/PB1199

Colorcon's globally available product line for the pharmaceutical industry includes:

Complete Film Coating Systems
Opadry®
Opadry® II
Opadry® AMB

Modified Release Products
Sureteric® Aqueous Enteric Coating System
Surelease® Aqueous Ethylcellulose Dispersion

Monogramming Inks
Opacode®
Opacode® WB

Excipients
Starch 1500® Partially Pregelatinized Maize Starch

Additional Products
Opaspray® Color Coating Dispersion
Opatint® Food Coloring System
Opaseal® Sealant Coating Product
Opaglos® Tablet Core Sealant Product
Opalux® Color Coating Product

FD&C and D&C Aluminium Lakes

Pigment Blends

Colorcon®
Member of the Berwind Pharmaceutical Group

PHARMACEUTICAL EXCIPIENTS

CEOLUS®

CELLNEX®

PC-10

Trehalose

KICCOLATE®

AsahiKASEI

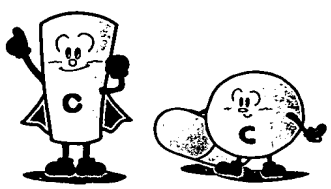
ASAHI KASEI CHEMICALS

Product overview

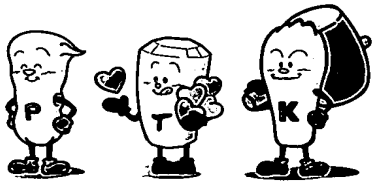
Product	Chemical name	Pharmacopoeia listings[a]				Main function
		USP/NF	Ph.Eur.	JP	JPE	
CEOLUS® KG	Microcrystalline cellulose (MCC)	●	●	●		Dry binder
CEOLUS® PH	Microcrystalline cellulose (MCC)	●	●	●		Binder, Filler, Granulation aid, Flow aid, Disintegrant
CEOLUS® RC	Microcrystalline cellulose and Sodium carboxymethylcellulose (MCC and CMC-Na)	●			●	Suspension stabilizer
CELPHERE®	Microcrystalline cellulose (MCC)	●	●	●	●	Spherical seed core
PC-10	Pregelatinized starch	●	●		●	Binder, Filler, Granulation aid, Disintegrant
Trehalose	Trehalose				P/U[b]	Binder, Filler, Taste masking
KICCOLATE™	Croscarmellose sodium	●	●	●		Disintegrant

[a] Circles indicate listing in:
USP/NF: U.S. Pharmacopeia & National Formulary
Ph.Eur. : European Pharmacopoeia
JP : Japanese Pharmacopoeia
JPE : Japanese Pharmaceutical Excipients

[b] Precedent use approvals are available.



Features	Page
CEOLUS® KG is the world's most compactible MCC dry binder, dwe to an inherent effect of its distinctive rod-form particle morphology. With its high compactibility, it is particularly effective in reducing the tablet size of large-dose and low-compactibility drugs, also for compression of pressure-sensitive drugs, coated-granules, and orally dispersible tablets.	3
CEOLUS® PH is an established standard for MCC and one of the most widely used pharmaceutical excipients. It provides ideal function and performance in various pharmaceutical applications, including direct compression, wet granulation and dry granulation, and extrusion and spheronization.	4
CEOLUS® RC is a homogeneous co-processed product containing MCC and CMC-Na as hydrocolloid. It stabilizes suspensions of active ingredients in liquid dosage formulations, and thus is used as a suspension stabilizer for syrups and dry-syrups.	4
CELPHERE® is a 100% MCC spherical seed core for drug layering and film coating. It is high in mechanical strength and water absorption and is an optimum substrate for a wide range of drug layering and coating systems.	5
PC-10 is a non-soluble pregelatinized starch which retains the shell structure of starch grains but has an extremely low water-soluble content. It is a versatile excipient; it serves as dissolution enhancer, granulation aid, and stabilizer for moisture-sensitive drugs, and carrier for hygroscopic materials.	6
TREHALOSE is a non-reducing di-saccharide. It provides distinctive functions such as low reactivity with basic drugs, higher compactibility and faster disintegration than sugar alcohols, and effective taste masking.	7
KICCOLATE® is a cross-linked polymer of carboxymethyl cellulose sodium, which is known as a super disintegrant. Asahi Kasei is the worldwide sole distributor of Kiccolate® manufactured by Nichirin Chemical Industries, Ltd.	8

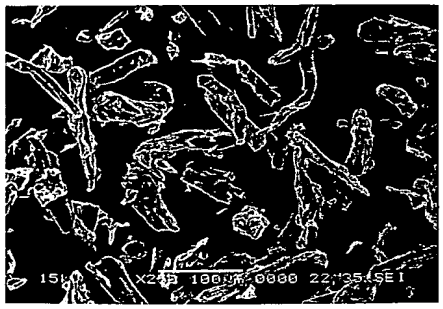


JQA-QMA10218

091-A

Microcrystalline Cellulose

CEOLUS® KG



CEOLUS® KG is an MCC dry binder with a distinctive rod-form particle configuration that provides incomparable compactibility, as a product of world-leading development and process technology at Asahi Kasei.

USP / NF	Ph.Eur.	JP
Microcrystalline Cellulose	Microcrystalline Cellulose	Microcrystalline Cellulose

Typical properties

Grade	Av. particle size (μm)	Bulk density (g/cm³)	Loss on drying (%)	Repose angle (degrees)	Package	
					Type*	Net weight (kg)
KG-802	50	0.21	2.0 - 6.0	49	A	15

*A: Polyethylene bag in kraft paper bag

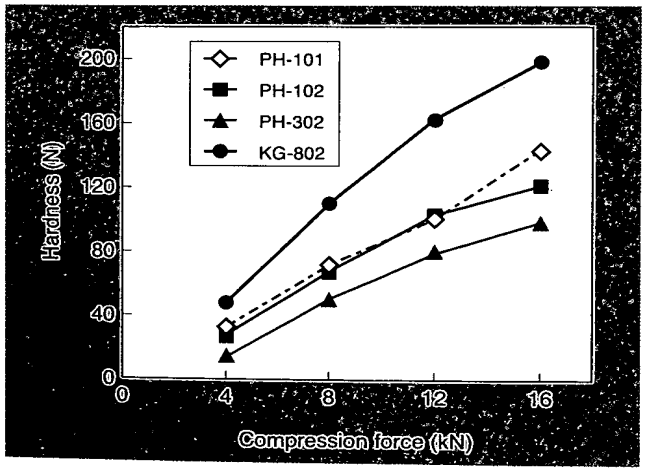
Note: All values are presented only for the purpose of basic reference and not as specifications.

Features and key applications

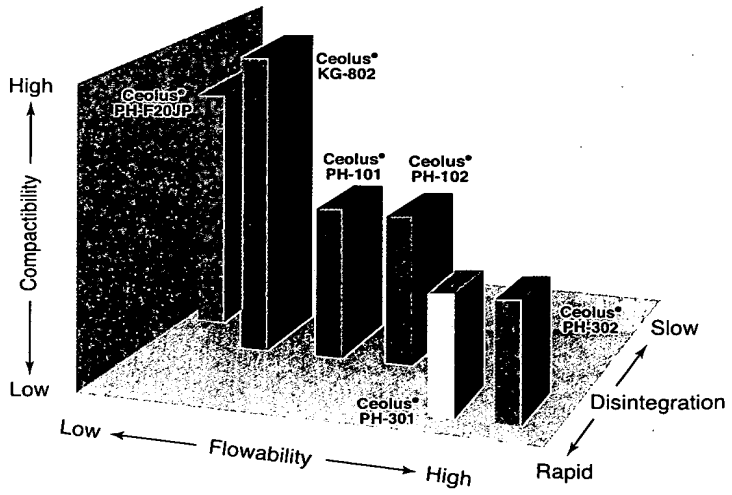
With its excellent compactibility, CEOLUS® KG-802:

- **Reduces addition amount requirement, enabling smaller tablets.**
- **Lowers compression force, facilitating the tableting of pressure-sensitive drugs such as enzymes, antibiotics and film-coated granules.**

●**Compactibility of plain tablets**

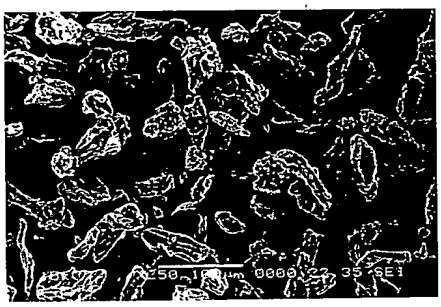


●**Tri-functional composite profile**



Microcrystalline Cellulose

CEOLUS® PH



The CEOLUS® PH MCC powder-grade series provides excellent, proven performance in a broad range of pharmaceutical applications.

USP / NF	Ph.Eur.	JP
Microcrystalline Cellulose	Microcrystalline Cellulose	Microcrystalline Cellulose

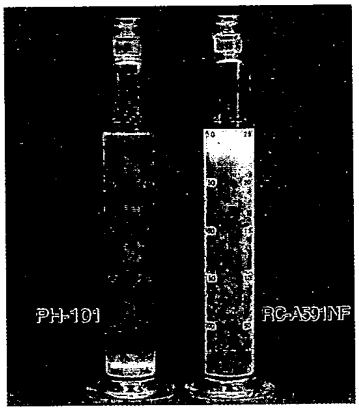
Typical properties

Grade	Av. particle size (μm)	Bulk density (g/cm³)	Loss on drying (%)	Repose angle (degrees)	Package	
					Type*	Net weight (kg)
PH-101	50	0.29	2.0 - 6.0	45	A	20
PH-102	90	0.30	2.0 - 6.0	42	A	20
PH-301	50	0.41	2.0 - 6.0	41	A	25
PH-302	90	0.43	2.0 - 6.0	38	A	25
PH-F20JP	20	0.23	≤ 7.0	≥ 60	B	20

*A: Polyethylene bag in kraft paper bag B: Polyethylene bag in cardboard box
Note: All values are presented only for the purpose of basic reference and not as specifications.

Microcrystalline Cellulose
and Sodium Carboxymethylcellulose

CEOLUS® RC



CEOLUS® RC is a colloidal product which consists of MCC co-processed with sodium carboxymethylcellulose as hydrocolloid.

USP / NF	JPE
Microcrystalline Cellulose and Sodium Carboxymethylcellulose	Microcrystalline Cellulose and Sodium Carboxymethylcellulose

Typical properties

Grade	Assay for MCC (%)	Assay for CMC-Na (%)	Viscosity (mPa·S)	Package	
				Type*	Net weight (kg)
RC-A591NF	≥ 80	8.30-13.70	39-91	A	25

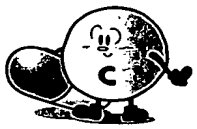
*A: Polyethylene bag in kraft paper bag Note: All values are presented only for the purpose of basic reference and not as specifications.

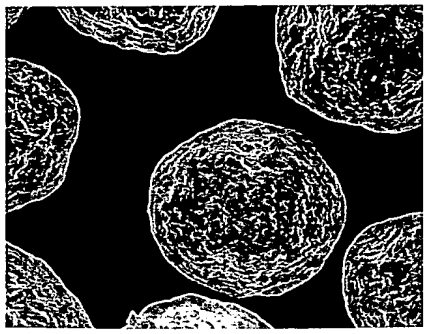
Features and functions

- **Suspension stabilizer:** Stabilizes oral and topical suspensions.
- **Granulation aid:** Improves dry-syrup granulation.

Microcrystalline Cellulose Spherical Seed Core

CELPHERE®





CELPHERE® is a 100% MCC spherical seed core, used in manufacturing of granules for sustained-release, taste-masked and other special properties.

USP / NF	Ph.Eur.	SCP: JP	CP: JPE
Microcrystalline Cellulose	Microcrystalline Cellulose	Microcrystalline Cellulose	Microcrystalline Cellulose Spheres

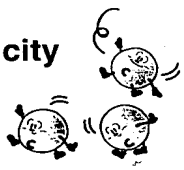
Typical properties

	SCP-100	CP-102	CP-203	CP-305	CP-507	CP-708
Particle size range (μm)	75~212	106~212	150~300	300~500	500~710	710~850
Sphericity	1.2	1.2	1.1	1.1	1.2	1.2
Bulk density (g/cm³)	0.66	0.83	0.87	0.97	0.97	0.93
Friability (%)	0.0	0.0	0.0	0.0	0.0	0.0
Water absorption (%)	130	100	100	110	70	65

Note: All values are presented only for the purpose of basic reference and not as specifications.

Features and functions

- **High mechanical strength**
- **Low reactivity**
- **High sphericity**
- **Fine and uniform particle size**
- **Optimum water absorption**



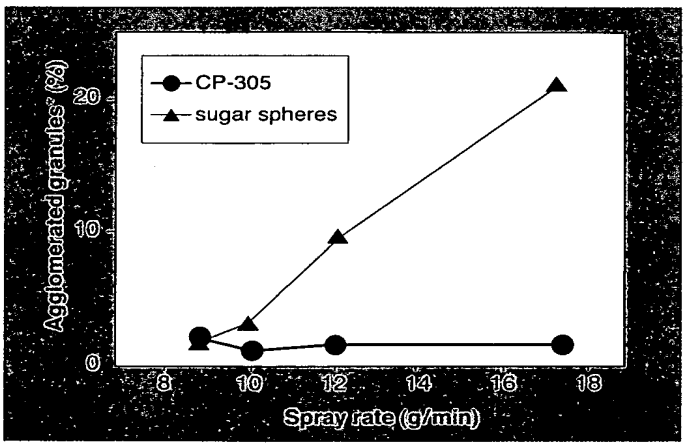
◆Reduction of particle agglomeration

With CELPHERE®, agglomeration during coating process is minimal. CELPHERE® makes it easy to manufacture drug layered and film coated granules and has distinct advantages over sugar spheres.

Formulation

- **Granulating machine:** CF-360
- **Seed cores:** CELPHERE®CP-305 or sugar spheres
- **Model drug:** Powdered sucrose (20% of core wt.)
- **Binder solution:** 3% HPC-L aqueous solution

●Agglomeration vs. spray rate



*Granules in agglomerates of 500 μm or larger, as percent of all granules.

Package

- Polyethylene bag in cardboard box
- 20kg net weight

Pregelatinized starch

PC-10

PC-10 is a natural excipient manufactured by thermal treatment of raw corn starch. It is inert, and high in water-absorbing and pH-independent disintegrating properties. It swells in water without dissolving.

USP / NF	Ph.Eur.	JPE
Pregelatinized Starch	Pregelatinised Starch	Partly Pregelatinized Starch

Typical properties

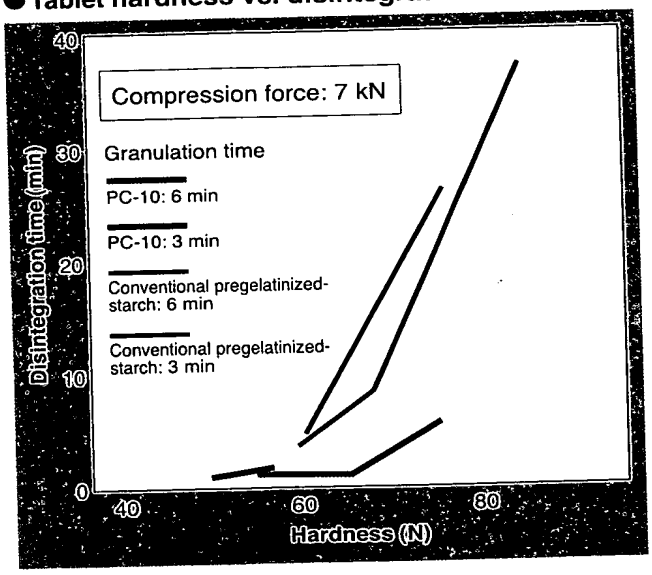
Av. particle size	70 μm	Water-soluble content	≤ 3%
Repose angle	38~40 Degree	Water-holding capacity	3.7 g/g
Bulk density	0.5 g/cm³	Swelling volume in water	8~9 cm³/g

Note: All values are presented only for the purpose of basic reference and not as specifications.

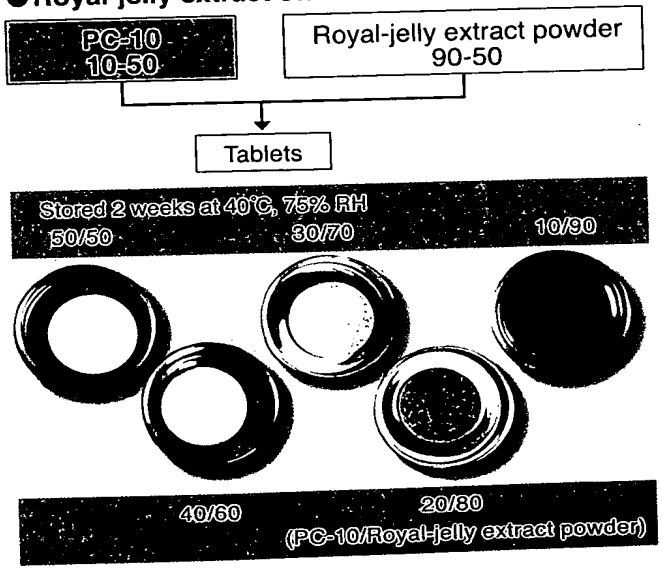
Features and functions

- Stabilizer for moisture-sensitive drugs
- Carrier for hygroscopic ingredients
- Dissolution enhancer
- Granulation aid
- High flowability

● Tablet hardness vs. disintegration time



● Royal-jelly extract stabilization



Package

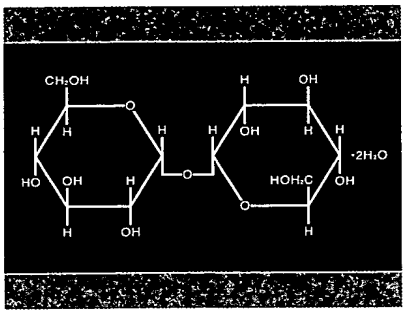
- Polyethylene bag in kraft paper bag
- 20kg net weight

Trehalose

Trehalose

Trehalose is a non-reducing di-saccharide, used for pharmaceutical products as a compactible sugar-type filler and as a taste masking agent, and is marketed worldwide by Asahi Kasei for these applications.

● Chemical structure



General properties

Melting point: 97℃ **Heat of fusion:** 57.8 KJ/mol
Sweetness: 45% that of sucrose
Hygroscopic: None at less than 90% RH
Digestive: 4 kcal/g
Solubility: 68.9 g (anhydride) / 100 g water (at 20℃)
Solution stability: Excellent against pH, heat, amino acids

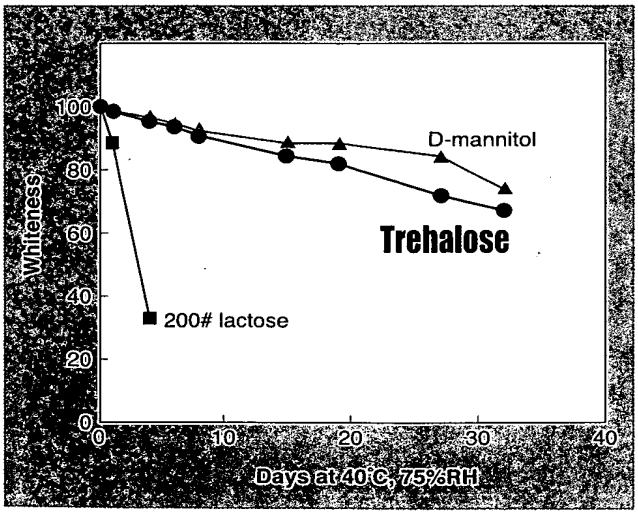
Grade	P	G
Form	Powder	Crystalline granule
Application	Solid dosage	Liquid dosage

Note: All values are presented only for the purpose of basic reference and not as specifications.

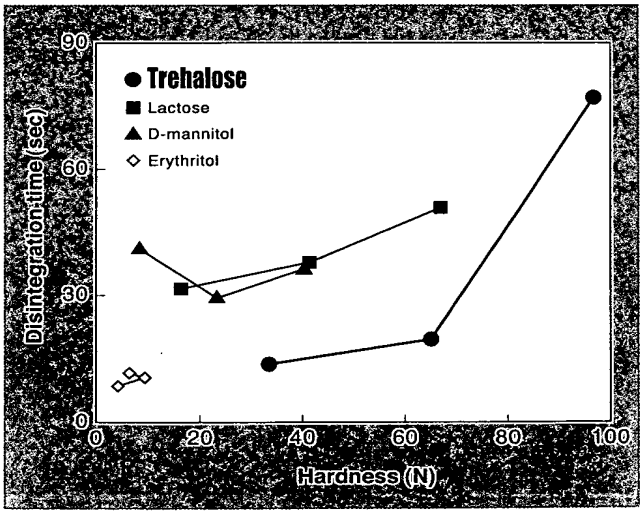
Features and functions

- Low reactivity
- Non-hygroscopicity
- Heat and pH stability
- Compatibility with basic drug
- High compactibility
- Taste- and smell-masking effect

● Aminophylline storage test



● Hardness vs. disintegration time of plain tablets



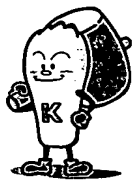
Package

● Trehalose P: Polyethylene bag in carton box
Trehalose G: Polyethylene bag in kraft paper bag

● 20kg net weight

Croscarmellose sodium

KICCOLATE®



KICCOLATE® is a croscarmellose sodium, which is widely used in oral pharmaceutical formulations as a disintegrant for tablets, capsules, and granules. Asahi Kasei Chemicals is the worldwide sole distributor of Kiccolate®, manufactured by Nichirin Chemical Industries, Ltd.

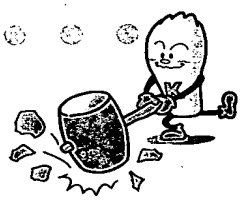
USP / NF	Ph.Eur.	JP
Croscarmellose Sodium	Croscarmellose Sodium	Croscarmellose Sodium

Typical properties

Grade	Bulk density (g/cm³)		Partide size	Settling volume (cm³/g)
	loose	tapped		
ND-200	0.44	0.65	≤5% on #200	15
ND-2HS	0.45	0.69		23

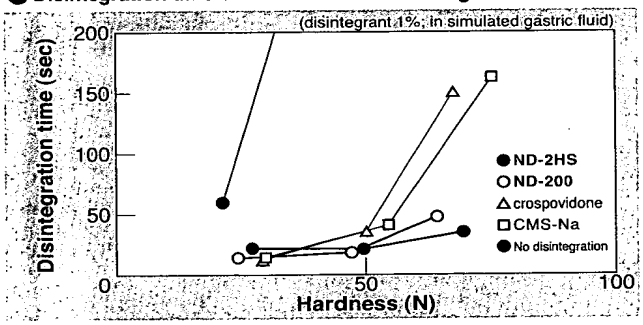
Note: All values are presented only for the purpose of basic reference and not as specifications.

Features and functions

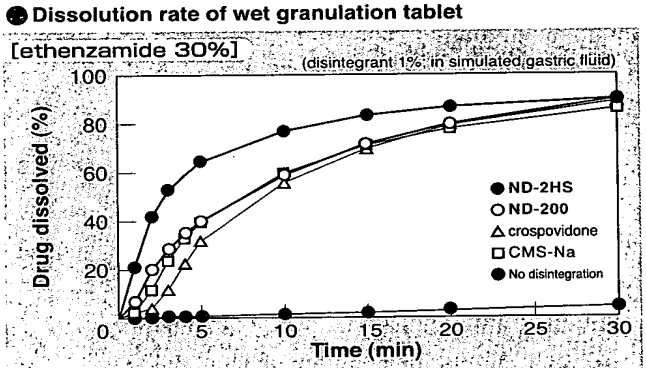


- Rapid disintegration and dissolution
- Consistently high quality
- Effective at low use levels
- Superior stability

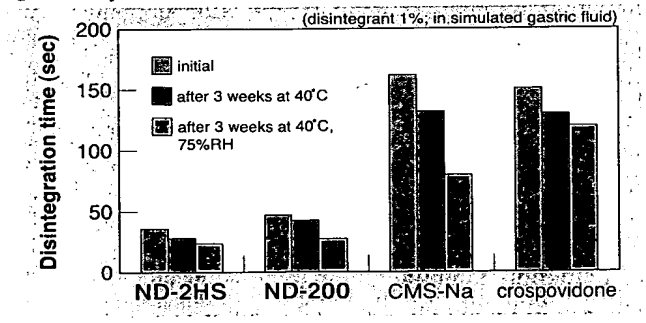
● Disintegration time of ethenzamide 30% wet granulation tablet



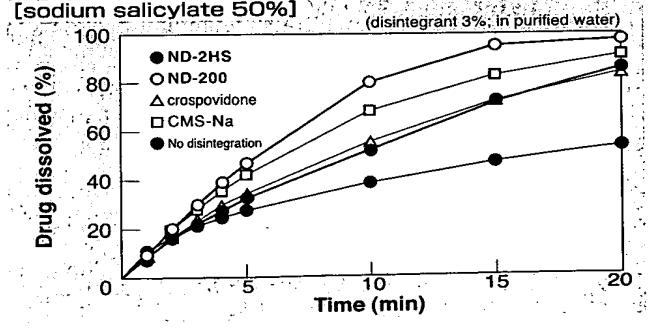
● Dissolution rate of wet granulation tablet



● Stability data of ethenzamid 30% wet granulation tablet



[sodium salicylate 50%]



Package

- Polyethylene bag in fibre drum.
- 25kg net weight

Notes and Precautions

Important precautions on handling and use

- Consult Material Safety Data Sheet (MSDS) before handling and/or use.
- May form explosive air-powder mixture on dispersion in handling, use, or from accumulated deposits on horizontal surfaces.
- Avoid contact with eyes. In case of eye contact, rinse with water for at least 15 minutes and get medical treatment if irritation occurs or persists.

Disclaimer of warranty and liability

- All information in this publication is provided in good faith and believed correct, but Asahi Kasei Chemicals Corporation undertakes no obligation, liability, warranty, or other responsibility, express or implied, for its completeness or accuracy.
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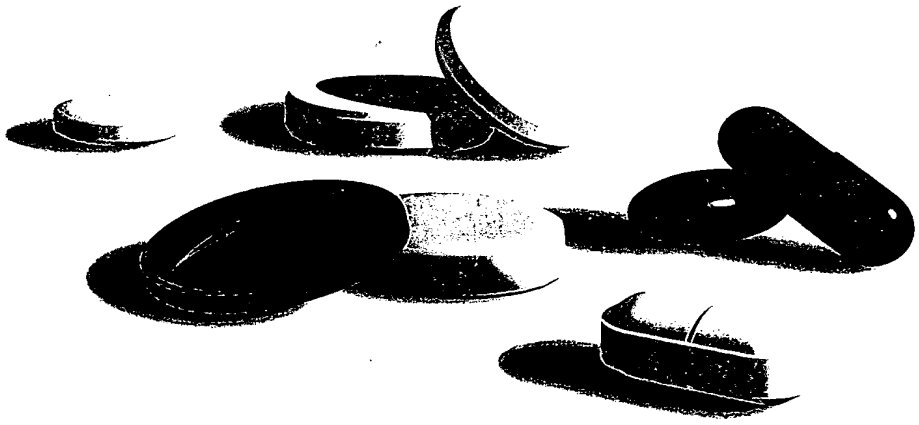

Asahi**KASEI**

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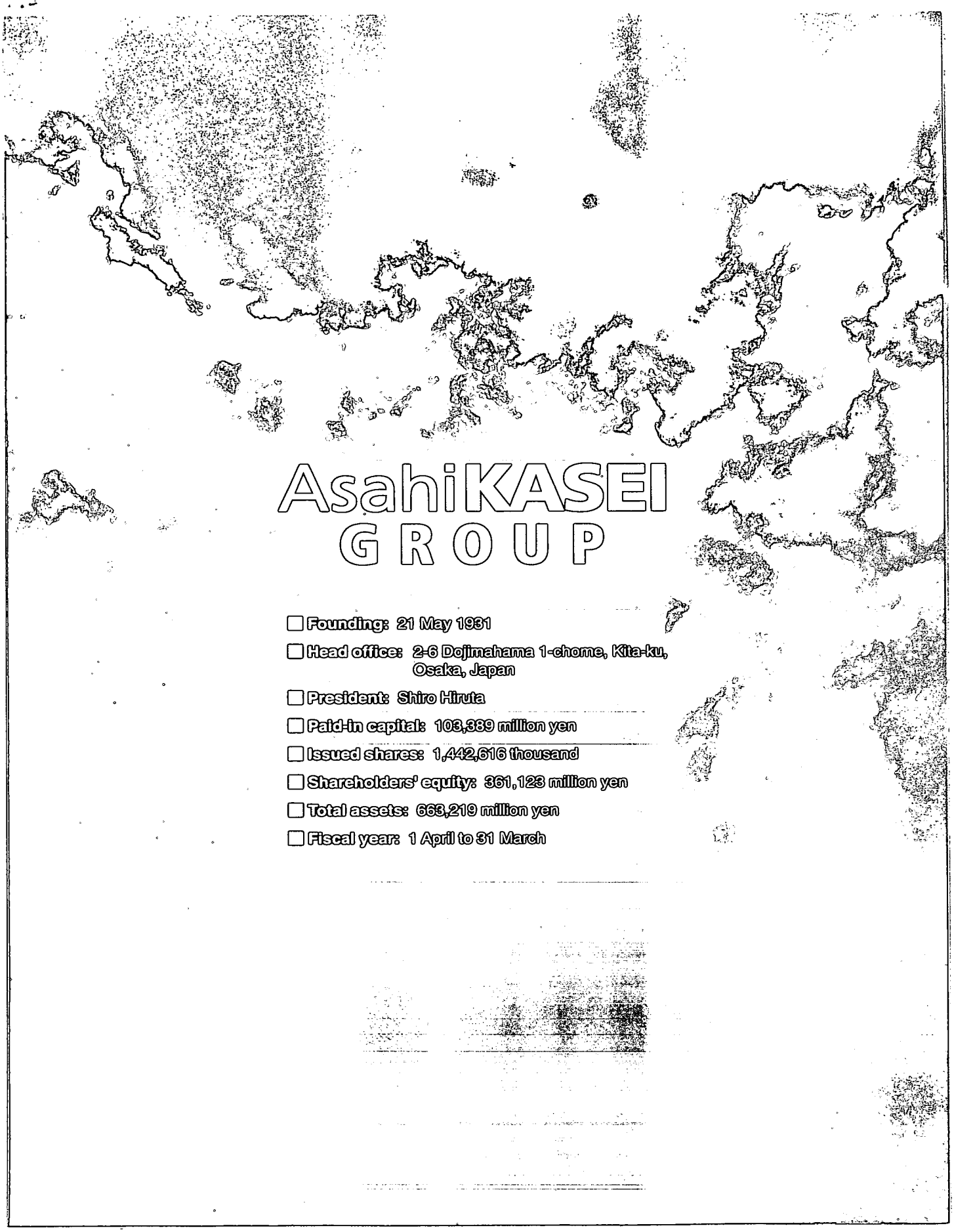


AsahiKASEI GROUP

- Founding: 21 May 1931
- Head office: 2-6 Dojimahama 1-chome, Kita-ku, Osaka, Japan
- President: Shiro Hiruta
- Paid-in capital: 103,389 million yen
- Issued shares: 1,442,616 thousand
- Shareholders' equity: 361,123 million yen
- Total assets: 663,219 million yen
- Fiscal year: 1 April to 31 March

AsahiKASEI GROUP

We the Asahi Kasei Group, through constant innovation ar advances based in science and the human intellect, will contribute to human life and human livelihood.

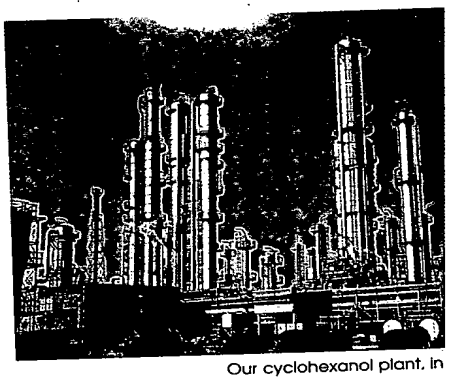
ASAHI KASEI CORPORATION

Summary of results, FY2005 to FY2006 (in millions of yen unless otherwise indicated)

Year ended	31 March 2006	31 March 2007
Net sales	1,498,620	1,623,791
Operating profit	108,726	127,801
Ordinary profit	104,166	126,507
Employees (person)	23,030	23,715

ASAHI KASEI CHEMICALS CORPORATION

Main businesses: Organic and inorganic industrial chemicals, synthetic resins (e.g. Stylac™, Suntec™, Tenac™, Xyron™), synthetic rubber, high-compound fertilizers, coating materials (e.g. Duranate™), latexes, pharmaceutical and food additives (e.g. Ceolus™), explosives, photopolymers and platemaking systems (e.g. APR™), separation and ion-exchange membranes, systems, and equipment.



Our cyclohexanol plant, in

Head office: 1-2 Yuraku-cho 1-chome, Chiyoda-ku, Tokyo, Japan

Asahi Kasei Plastic

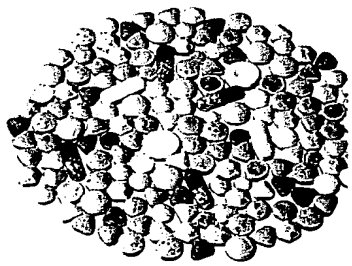
President: Taketsugu Fujiwara

Paid-in capital: 3,000 million yen

Total assets: 592,100 million yen (as of March 31, 2006)

Employees: 6,200 persons (as of April 1, 2007)

Shareholder: Asahi Kasei Corporation



Pharmaceutical tablets

ASAHI KASEI FIBERS CORPORATION

Main businesses:

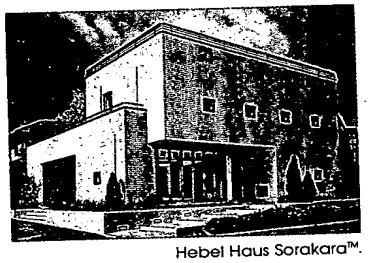
Roica™ polyurethane fibers, Eltas™ spunbonds, Lamous™ artificial suedes, Bemliese™ cupro nonwovens, AsahiBemberg™ cupro fibers, Leona™ nylon 66 fibers, polyester filaments.

Apparel made with Solo™ PTT filament.

ASAHI KASEI HOMES CORPORATION

Main businesses:

Design, supervision, and contracting for Hebel Haus™ homes and Hebel Maison™ condominiums and apartments; condominium and apartment operation; home renovation; realty; urban development.



Hebel Haus Sorakara™.

ASAHI KASEI PHARMA CORPORATION

Main businesses:

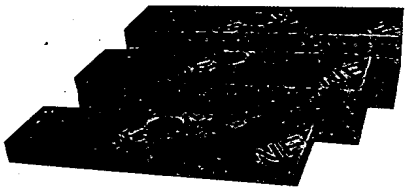
Pharmaceuticals, pharmaceutical intermediates, feed additives, diagnostics, dialysers and other medical devices.

Nutritional supplement by Fancl Corp. using Asahi Kasei coenzyme Q10.

ASAHI KASEI CONSTRUCTION MATERIALS CORPORATION

Main businesses:

Hebel™ autoclaved lightweight concrete, construction piles, Neoma™ foam and other heat insulation, artificial fishreefs.

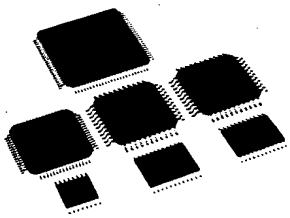


Neoma™ form insulation panels.

ASAHI KASEI ELECTRONICS MATERIALS & DEVICES CORPORATION

Main businesses:

Pimel™ photosensitive polyimide resins, Sunfort™ photosensitive dry-film resist, Hall elements, LSIs, glass fiber fabrics for printed circuit boards.



LSIs from Asahi Kasei Microsystems.

AsahiKASEI GROUP

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